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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,994	12/09/2002	Klaus-Ulrich Weithmann	DEAV2001/0073	6670
5487	7590	08/26/2004	EXAMINER HABTE, KAHSAY	
ROSS J. OEHLER AVENTIS PHARMACEUTICALS INC. ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			ART UNIT 1624	PAPER NUMBER
DATE MAILED: 08/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/065,994	WEITHMANN ET AL.
	Examiner Kahsay Habte, Ph. D.	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 August 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,3-8, 19 and 20 is/are allowed.
- 6) Claim(s) 2,9-12 and 21-23 is/are rejected.
- 7) Claim(s) 13-18 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. Claims 1-23 are pending.

### ***Response to Amendment***

2. Applicant's amendment filed 8/17/2004 in response to the previous Office Action (4/23/2004) is acknowledged. Rejections of claims 1-23 under 35 U.S.C. § 112, first and second paragraph (paragraphs 6-7 and 9b-9e) have been obviated. The rejections of the claims in items 8, 9a and 9f have been maintained.
3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. Applicants have to limit their invention to Group I (i.e. A = N).

### ***Claim Objections***

4. Claim 22 is objected because of the misspelled term "arthritides". It should read as arthritis.
5. Claims 17-18 are objected because claim 17 duplicates claim 12. Both claims 12 and 17 are drawn to a method of therapy of a degenerative joint disease and use the compounds of formula I or compounds of claim 2.

6. Claims 13-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims must be dependent in the alternate form. For example, claim 13 cannot multiply dependent on claim 12 and claim 3. See MPEP § 608.01(n).

***Response to argument***

Applicant's argument filed 08/17/2004 has been fully considered but it is not persuasive..

Applicants did not address this issue.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for therapy of a disease which is a degenerative joint disease, a disease of connective tissues, does not reasonably provide enablement for a method for therapy of a disease which is a chronic diseases of locomotor system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

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commensurate in scope with these claims. There has been recited a method for therapy of a disease which is a chronic diseases of locomotor system, but the specification is not enabled for such a scope .

Locomotor system deals with components of the structure/function relationships of bone, muscle and joints, the pathologic processes affecting these and the processes of repair and healing. The skeleton and skeletal muscles work together to allow movement. The brain controls the movements of the body, using information from:

- The eyes.
- The ears, including special canals, which give us a three-dimensional sense of motion.
- The muscles themselves, called 'muscle sense' or kinaesthesia.

### **The skeleton**

The skeleton is made up of 206 bones. Bones are a form of connective tissue reinforced with calcium and bone cells. Bones have a softer centre, called marrow, where blood cells are made. The three main functions of the skeleton are:

- **Support** - the body is supported and shaped by the skeleton; for example, upright posture would be impossible without a spine.

- **Protection** - our internal organs are protected by our skeleton, such as the brain inside the skull, the heart and lungs inside the ribcage.
- **Movement** - most skeletal muscles are attached to bones in opposite working groups, like the bicep and tricep muscles of the upper arm.

### **Muscle fibres**

Skeletal muscles operate under voluntary control. An example of involuntary muscles are those that line the digestive system. Skeletal muscles are made up of muscle fibres, bundled together. Each fibre can contract or relax on demand. All fibres contract together to shorten a muscle. The command to contract or relax is given by the brain and relayed to the muscle by nerves.

### **Working in pairs**

Generally, muscles move the skeleton by working in opposite pairs. For instance, if you bend your elbow, your biceps (muscles on the front of the upper arm) contract and the triceps (muscles on the back of the upper arm) relax. It works the other way if you straighten your arm - the triceps contract while the biceps relax. In some joints, like the shoulder joint, many different muscles are attached. This allows even greater freedom of movement.

### **Common problems**

Some of the more common problems of the locomotor system include:

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- **Arthritis** - problems within the joints, such as inflammation
- **Broken bones** - caused by falls or accidents
- **Slipped disc** - when cartilage in the spinal column shifts out of position.

In addition, bone disease, CNS disorders, personal injuries to the brain or spinal cord, etc. are some of the conditions that can cause chronic diseases of locomotor system.

Note that the movement of any parts of a body involves a signal from a central nervous system. Thus, the claim also covers any CNS disorders that affect the movement of a body. For example, Parkinson's disease is a central nervous system disorder, but it is covered under "diseases of locomotor system." Since diseases of locomotor system would cover problems in any of the above parts of the body arise from different origins, and differ significantly one from the other, an enablement rejection is proper.

Note that in the review article by Leeman et al. there is no mention of any method for prophylaxis or therapy of disease for locomotor system whose course involves an increased activity of matrix metalloproteinase.

#### ***Response to argument***

Applicant's argument filed 08/17/2004 has been fully considered but it is not persuasive.

Applicants did not address this issue.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 9-12 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a. In claim 2, the phrase "physiologically tolerated salt" is improperly dependent on claim 1. Claim 2 depends on claim 1, but in there is no mention of "physiologically tolerated salt" back in claim 1.
- b. Claim 2 is rejected because it fails to narrow down further the limitations of claim 1. Note that "compounds of formula I" as recited in claim 1 cover all the stereoisomeric forms of said compounds.
- c. In claims 10-12 and 23, the phrase "related chemical entity" is indefinite.

What related chemical entity? Related how? What is covered and what is not?

***Response to argument***

Applicant's argument filed 08/17/2004 has been fully considered but it is not persuasive.

Applicants have fixed the problem in claim 2 by inserting a definition of said phrase from the specification, but forgot to fix the problem in claims 11-12.

d. In claim 21, the phrase "chronic diseases of locomotor system" is not clear. What are covered and what are not? How can one tell if a disease is a chronic disease of locomotor system or not? Note that this is not a well-defined category.

***Response to argument***

Applicant's argument filed 08/17/2004 has been fully considered but it is not persuasive.

Applicants did not address this issue.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
August 24, 2004